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Minutes

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cc Mgmt:	Atkin John CHBS; Durand Robert CHBS; Huguet Patrick CHBS; Kuhn Eric CHBS; Sozzi Dino CHBS; Wilde David CHBS; Evans David GBJH; Lawrence David CHBS; Rezende Maercio BRSP; Smits Piet GBGU; Taylor Don CNHK; Woods Bob USUW	
cc Tech. Mgmt:	Angst Max CHBS; Barnes Jasper CHBS; Berengier Jean FRSC; Botham Phil GBAP; Campbell Peter GBJH; Casola Franco ITMI; Castle DianeGBGU; d'Hondt Christian CHBS; Dickson Gary USGR; Diriwaechter Georg CHBS; Doe John GBAP; Doppmann Franz CHBS; Drost Dirk USGR; Flattery Marian CHBS; Flores Maurilio MXMC; Guthrie Andrew CNHK; Kim YongWhan KRSL; Konradt Manfred DEMT; Leadbeater Andy CHBS; Leadbitter Neil GBJH; Mcfarland Janis USGR; Mittermeier Ludwig BRSP; Moss Michael USGR; Ohtomo Hidero JPTO; Parr-Dobrzanski Bob GBAP; Richards Christopher GBGU; Sadler David GBJH; Schwager Luis BRSP; Stypa Marian CATO; Winten Rowley AUSY; Yoder Joe CHBS; Zoschke Andreas CHBS	
Concerning:	**Development Committee Meeting, Basel** **10 September 2002**	

EXHIBIT
ATKIN
15
10/5/10 JW

Summary of Main Points

- **SYN 449 280**: In order to stay on the fast track, the Product Evaluation Team has been authorised to order animals for the 2-year rat study ahead of the formal Stage 3 promotion. It was made clear that this did not pre-empt the decision in December 2002.
- **Amistar Xtra**, a product containing 200 g/l azoxystrobin and 80 g/l cyproconazole which will be used on Wheat, Barley, Oats, Rye in several countries has been released for first sales.
- **Thiamethoxam**: The review of the registration status in NAFTA shows that approx. $ 50 Mio in potential sales are currently awaiting registration by EPA. The timing of when success will be achieved is uncertain and depends on many technical and political factors including the speed EPA can clear the work backlog.
- **Mesotrione carryover**: new findings indicate that although the issue appears manageable, problems could occur under adverse conditions (over spraying, dry soil, etc.) with products containing higher use rates.
- **Camix and Lumax** (mesotrione + S-MOC or S-MOC/atrazine) have been released provisionally for one year. A comprehensive stewardship plan has been requested.
- **Mesotrione - Ames testing**: a practical solution to replace the current expensive measures remains elusive. An approach has been agreed that may provide a basis for further discussion with EPA.
- **NOA 407 855 - tox issues**: the initiation of a repeat chronic dietary mouse study has been approved. In (the unlikely) case that the current gavage study should turn out to be meeting regulatory requirements, the repeat study would be terminated.
- **Methidathion - user safety**: a new operator safety study indicates that considerable investments would be required to support the AI in Europe and the decision has been taken, to agree the phase out with the authorities.
- **Chlorothalonil - EU re-registration**: at least $ 4.5 Mio will have to be invested to complete the European re-registration. This is in addition to >$ 13 Mio spent already. A number of issues remain that will require further attention.
- **Acanto - earthworm**: good progress has been made in understanding the earthworm issue. It is expected that data will show populations to recover quickly enough to meet registration requirements.
- **Acanto Dos** (amistar + hexaconazole) has been provisionally approved to first sales for 1 year.

1. Minutes of the last Meeting

Action 6.2: Tralkoxydim/EPA: the team has considered the implications of the ongoing review on the position in Canada and concluded that withdrawal from the review process risks to trigger more questions than continuing the process and would likely accelerate the review process in Canada. The team will therefore pursue the current EPA review according to the agreed business and regulatory strategy.

Action 10: GIS algorithms

10.1: There are no viable IP options. The fall back is to make it clear to the key Euro regulators that these approaches are Syngenta inspired and developed. Accordingly, we have planned or held meetings with a number of regulators to talk through the technical approach and to ensure that key regulators and relevant scientists continue to understand that Syngenta is leading the way in these areas of spatial regulatory and stewardship science.

10.2: There has been one meeting of the FOCUS Landscape and mitigation group so far, it appears that the group's timetable is likely to require us to start to share this algorithm in March. Plans for this and associated publications are well developed.

10.3: P. Hendley raised with Dow and Bayer who both refused to offer anything above a "quid pro quo" for the study; as feared, they realized they could access similar technology from WEI without paying a premium. We are now making efforts to minimize the potential for damage if they devise alternative approaches.

Action 11.2: The project has been terminated and a closure report is available. Research informs that they have no plans for further invention work around the herbicidal mode-of-action of the metabolite of azoxystrobin.

Action 13: HR/project management training initiative: HR have established a Steering Group that will meet for the first time Oct. 11.

2. SYN 449 280: ordering of animals for chronic tox studies

The excellent technical & strategic corn portfolio fit has been confirmed. SYN-449280 at ~ 200 g A.I./ha plus s-MOC at 0.75 g AI/ha appear a superior PRE/VEPO-em one-pass corn herbicide. It provides reliable, selective, season-long control of key annual grasses and dicots replacing triazines in an s-MOC mix.
The key product concept is thus fully confirmed. Points to note:

- Biology, manufacturing, formulation and patent are clear
- Toxicology is challenging, but manageable
- Environmental safety is critical for WEU; a more definite assessment can be made in early November
- Business – the preliminary case looks positive and more information will be available by early Nov.
- There are several potential upsides

Based on the available data, the team is working towards a Stage 3 promotion in December and proposes to maintain the project on the fast track.
The 2-year rat study is time critical and animals need to be ordered in October for the study to start timely. The last date to cancel the order is in early November.
The animals will cost approx. $ 30k, i.e. not a major investment. Some animals could probably be used for other purposes if the study could not go ahead as planned, but not all of them.

Discussion and conclusions:
DeCo supports the fast track approach, but reminds the team that any enabling actions taken ahead of the formal Stage 3 promotion should not pre-empt a thorough review in December.

2.1. Action: DeCo supports the ordering of animals for the 2-year rat study, but requests the team to review the situation once more before the order becomes final. A. Zoschke/early Nov.

2.2. Action: J. Atkin will be briefed and asked for support in principle. V. Anthony/early Nov.

3. Reporting potentially referable findings (PRF)

The current process has been approved by DeCo in May 2001. Practical experience has indicated a need for some revision.
Policy:

- To comply with all relevant legislation at all times
- To apply the principles even where legislation does not exist.

Scope:

- Applies to all data generators and field staff
- Is applied by all in Development

Commitments:

- Clear PRF management processes in place
- Decisions made are recorded (audit)
- Staff are aware of their PRF reporting obligations
- Formal training is given to all staff (line managers accountable)
- Third parties comply with our policy

Discussion and conclusions:
The guideline also applies to data generated on our behalf by third parties. Information that is in the public domain, on the other hand, does not need to be reported. The same applies to obvious product misuse, such as suicide.
The process is currently well understood in NAFTA and in Europe, but less so in other places. It was agreed that we need to stipulate clear time periods within which information must be reviewed and acted upon.
For AIs which we introduced, but for which we are no longer the sole producer, there are no clear rules and the situation has been handled case by case. For AIs in which we maintain a serious interest we will inform the authorities if we are in legal possession of pertinent information.

3.1. Action: Where local legislation does not provide specific guidance, periods of 90 days will be stipulated in the guideline for internal reviews and for taking further action. J. Street/end Sept. 2002

3.2. Action: The new Guideline will replace the existing one with effect from 10.9.02.

4. White Book

The White Book is an Intranet document which contains a wealth of information useful to colleagues working on development projects. It describes roles and responsibilities, defines primary contacts and relationships between functions, regions & HQ.
The Development Project Portfolio process and the involvement of the various functions are explained and guidance is provided so that system-related requirements (SYPOS/PIT) are well understood.
Overall, the site should facilitate communication within the complex Syngenta organisation. Currently major functions and processes are covered – missing information will be added in due course.
The site enables on-line feed-back of comments and suggestions for improving processes. These will be collected by the project leader and following discussion and consultation, will be incorporated into the document. The 'White Book' will thus remain a live document and always reflect the latest practices.
The document can be found under: http://global1.pro.intra/devpmgt/

5. Amistar Xtra: release to first sales

The product contains 200 g/l azoxystrobin and 80 g/l cyproconazole and will be used on Wheat, Barley, Oats, and Rye. Introductions are planned in:

- 2003: UK, Argentina
- 2004: France, Germany, Netherlands, Austria, Hungary, Italy, Ireland, Switzerland, Spain, Chile
- 2005: Brazil, Belgium, Australia, Japan

Incremental sales are forecast to be $ 2.5 Mio in 2003, increasing to $ 19 Mio in 2010.
The objectives of the project were to offer an in house solution in case of resistance build up in cereals *(Septoria tritici, Septoria nodorum)*, and to gain business with a ready mix offer to the "less technical" farmer segment as Amistar is mostly positioned in "progressive technicians".
The product will also enable the phase out of hexaconazole/Amistar Ter in 2004.

The label will state 'Xn Harmful'. This is as predicted and consistent with other products containing a triazole and thus not considered an issue in cereals. As far as ecotoxicology, operator safety and expected residues are concerned no issues have been identified. The product will be formulated and packed in Grangemouth where there is considerable experience with fungicides.

Discussion and conclusions:
There was some concern over the use of azoxystrobin in combination with an AI that required a label warning. Alternatives had been considered, but rejected either for performance reasons (hexaconazole) or because they would not have represented an improvement with regard to the safety profile (tebuconazole).
Some concerns were also expressed about the way new formulations were started and whether the longterm environmental/tox profiles are fully taken into consideration.
Whilst some decisions may have been taken in haste during the merger, the processes that are now in place are thought to provide ample opportunity for discussion and review. New formulation projects will generally be discussed and defined early in the year by the PLT, will have to gain the support of the Product Line and relevant Regions, and will ultimately have to be approved by the Portfolio Review Board.
The need for continuing the investment in hexaconazole was also questioned, but it became clear that this was required to effect a smooth transition from Amistar Ter to Amistar Xtra.

5.1. Action: DeCo releases Amistar Xtra to sales as proposed.

6. *Thiamethoxam: registration status in NAFTA*

Janis Mcfarland presented the topic. Also present from NAFTA was P. Hertl and P. Rose form HAES participated via phone.

Thiamethoxam is important to NAFTA and is expected to contribute significant additional business.
Seed treatment was the first important project and the registration was obtained in Dec. 2000.
The first difficulty encountered was that EPA was reluctant to consider any further uses. PMRA in Canada had also decided against granting the registration of foliar uses.
Following intensive negotiations and attainment of status as an 'OP Alternative', EPA officials indicated a willingness, to review further applications. The process was, however, hampered repeatedly by personnel fluctuation, broken promises and policy changes at the agency.
In May 2001 foliar/soil uses in cucurbits, fruiting vegetables, cotton, pome fruits, tuberous and corm crops were also received:
Thiamethoxam was, however, as another 40 chemical applications, not included in the 2002 work plan. This was mainly due to a backlog of work at the agency. This means that approx. $ 50 Mio of additional sales (Flagship 25W/.22G Meridian 25W/.33G) are blocked in the registration process.

Short Term Strategy (2002 – 2003): corn ST, pecans, coffee IT, ornamentals

- Risk Cup Overflowing: we will refine the risk assessments
- Groundwater Studies have been initiated in MI and GA.
- Convince EPA to Work on 'Uses with Low Dietary Exposure': corn ST, pecans, coffee import tolerance and ornamentals
- Reduce rates to below groundwater standard where feasible
- Convince EPA that new rates will not impact overall water risk
- Use interim information on groundwater & market shares to give EPA confidence to proceed

Mid - Term Strategy (2003 - 2005): leafy veg., brassicas, grapes, potato ST, IR-4, golf/sod

- Delete foliar applications to fruiting vegetables (except peppers) and cucurbits.
- Submit soil only application residue program on key drivers: fruiting vegs, leafy and cole vegetables.

- Push EPA groundwater study (MI/GA) review to reduce EEC vs DWLOC.
- Complete turf intercept and uptake studies (high rates)

Long Term Strategy (2006 - 2007): residential turf, termite / general pest, improve use patterns

- Pursue company objective to remove Q*, improve overall toxicology picture (DNT, 2-gen repro, etc), open risk cup
- A robust toxicology case will be available in Q4 2004 (if data support)
- The submission of the new toxicology data should be made in 2004, but possibly as late as 2006 if the EPA Work Plan continues to prove a barrier.
- Best / Worst Case: Review in late 2006 – more likely 2007/08 with the current EPA backlog

Currently, corn seed treatment is number 1 registration priority and NAFTA believe to be on track for registration by October 2002. A strategy that envisages more than 20 follow-up meetings with all levels at EPA between June and October and orchestrated user support has been pursued.

Additional new uses appear possible, if

- EPA accepts market share information (apples).
- If EPA accepts DEEM refinements with foliar use deletions (fruiting veg. and cucurbits).
- Soil only residue program data proves supportive.
- EPA continues use of current consumption database.
- There are no surprises in the water data
- Additional uses make EPA's 2003 Work plan

Discussion and conclusions:
It seems obvious that many things will have to go right, if all objectives are to be met.
L. Smith reported that EPA is currently funding a study concerned with finding the best way of extrapolating from animal studies to human risk assessment. The results of this study will provide EPA with a solid basis for handling Q* issues, but there is concern that the agency may be reluctant to continue with making case-by-case judgments in the meantime. The earliest that the new approach will be adopted in practice is in late 2004.
We do not have good visibility of the strategy Bayer Crop Science is pursuing at present. Given that there is a potential risk that the agency will combine products with a comparable mode of action into a cumulative risk assessment, it would be helpful to know more.
Also, since thiamethoxam is not the only AI with Q* problems, it was felt that experience gained will be valuable in establishing a framework for handling these issues.
An aspect which has not featured prominently so far is operator safety; there are some indications that EPA will take a closer look at this in future and that this could prove yet another challenge.
It was obvious to DeCo that the project is given the required attention in NAFTA and that considerable progress has been made. The team is encouraged to marshal all expertise available inside the company and external to achieve the best possible results.

7. Mesotrione - carry-over: status

Commercial experience with CALLISTO (2001 applications and 2002 rotational plantings)

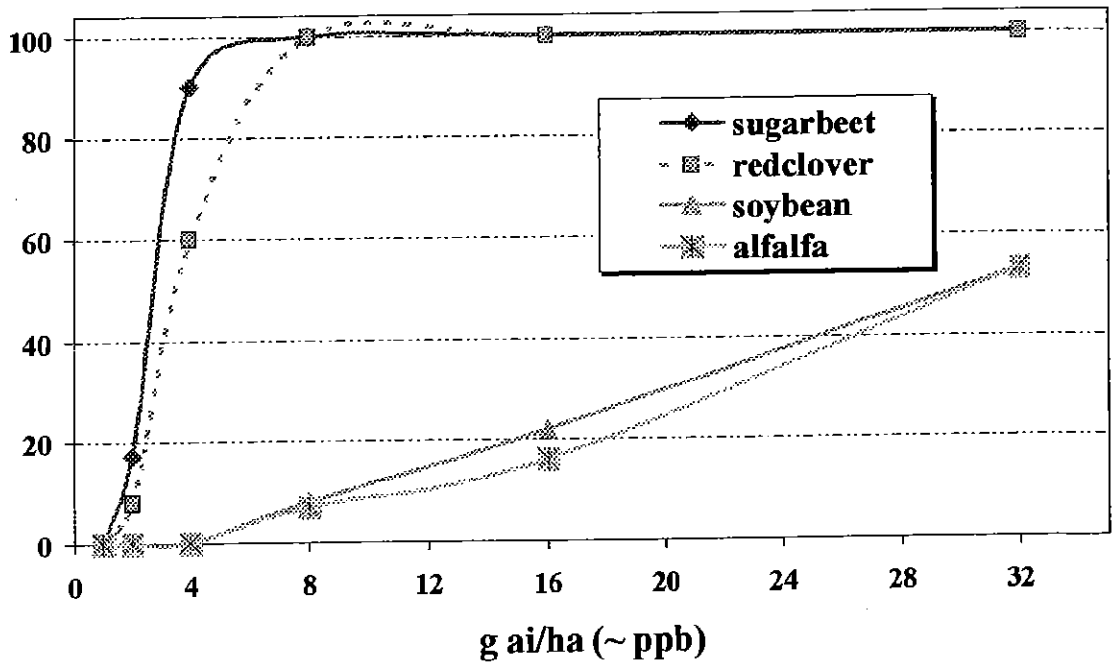
In 2002 the only rotational cropping complaints from commercial CALLISTO use were on sugar beet, pea, red kidney beans, and snap beans – crops have already been removed from the label. In total there were approximately 10 occurrences and compensation of about $ 600k had to be paid. We do not believe that the image has suffered as a consequence.
This experience proves, however, that mestorione carryover can occur in a commercial setting and that it can occur with applications rates as low as 105 g AI/ha (CALLISTO application rate).
No carryover was observed to soybeans following CALLISTO applied in 2001. Total use was 800,000 acres much of which would have been rotated to soybeans.

Crop Sensitivity

Based on various glasshouse assays, the no effect levels (NOEL) for mesotrione residues in soil for various rotational crops are: sugar beet, red clover (1-2 g AI/ha); soybean, alfalfa (4-12 g AI/ha); canola (8-16 g AI/ha) and cotton (16-32 g AI/ha). Soybeans are therefore around 4x less sensitive to mesotrione than sugar beet.

All carryover work and rotational crop positioning has been based on the acid and shows:

- 105 g AI/ha post-em or 225 g AI/ha pre-em give a low risk of carryover to soybeans at realistic re-plant intervals
- There appears to be an acceptable margin of safety for carryover to soybeans when mesotrione acid is applied at 225 g AI/ha pre-em or 105 g AI/ha post-em
- Safety margin is not 2X in some cases, especially if dry
- Callisto is acceptable as labelled



LUMAX and CAMIX, the new products, can be applied at rates delivering up to 225 g AI/ha of mesotrione. The products will be applied mainly pre-plant and pre-emergence with a small proportion being applied very early post emergence. This is at least 4 weeks earlier than CALLISTO applications and gives at least one extra half-life period. The risk from the rates of mesotrione in LUMAX and CAMIX should therefore be equal to CALLISTO use. This has been confirmed in actual carryover trials and in sites, which have been chemically analysed. At most field carryover trial sites we have observed good safety margins from 2x rates but the results from the NRTC (Illinois) trials show that there will be occasions where the safety margin is narrow.

Assumptions Made With LUMAX / CAMIX

- Cu-salt behaves like the acid relative to soil persistence.
- LUMAX is applied at a higher rate (2x higher), but an earlier application timing will cancel this relative to carryover risk

Basis for assumptions:

- DT50 determination in the laboratory, showed a similar decay curve for both the acid and the Copper salt.

- LUMAX use rate is ~ 2x higher than Callisto (105 vs 225 g AI/ha = 2.1 x)
- LUMAX is applied on average 4 weeks earlier (PRE vs E-Post).
- Soil DT50 for mesotrione acid in field studies 11-29 days (>1 half-life)
- Net effect = extra time (earlier application date) more than compensates for higher application rate.
- Net/net = no increased risk of carryover to soybeans with LUMAX / CAMIX compared to Callisto (a good overall assumption, as long as copper = acid)

Yellow Flag
Results in 2002 at one field location in Illinois raised concern about copper salt:

- Applied late to bare soil, very dry
- No damage to soybeans at 150 or 188 g AI/ha, damage at 225 g AI/ha

This raised the question whether the Cu-salt behave like the acid in all soils and under all environments. If the copper salt is not an issue then the current use recommendations are acceptable.

Study / Activity	Due date
Bioassays / chemical analysis of 20 new field samples (Cu vs Acid)	End Sept
Physchem studies / data analysis	End Sept
Glasshouse DT50 comparisons in different soils and moistures	Interim end Sept, end Oct
Soybean variety tolerance	Interim end Sept, end year
Deterministic modelling data	End of year (best case)
EDTA use in spray tank to remove Cu	End Sept
EDTA efficacy (esp. post-em)	G/H end Oct, field (SH) Jan
Decision point for launch scope	End Sept

A range of studies has been initiated to investigate if copper is a significant effect and if so, ways of managing it:

If the copper salt is an issue, a risk analysis and management plan will be put together at the end of September 2002; options that exist:

- Limit the rate to e.g. 5 pints (188 g AI/ha)
- EDTA (water softener) use in sensitive areas, by rate or overall
- Limit by soil type (pH, OM, CEC)
- Limit geography (dry areas)
- Limit to pre-plant and pre-em only

Further developments:

- Soil sampling and analysis of 2002 applications in autumn 2002 and spring 2003 (trials and commercial)
- Carryover trials in soil treated in 2002 (data available in July 2003)
- Geospatial risk analysis (March 2003)
- Autumn 2003 sampling of critical areas
- Recommend most tolerant soybeans if required
- Initiate the development of new formulations of Lumax and Camix without Copper salt

Conclusions and recommendations:
No explanation can be offered for a potential influence of copper on the carryover of mesotrione. Given the very low concentration of about 90 pbb in the soil, an effect on the microbial activity is not likely. It was postulated that the addition to the spray tank of EDTA, a common water softener, could neutralise the effect of copper. The approach could work in practice, but the effects on the biological efficacy would also have to be evaluated.
In NAFTA, sales for the next season will begin in October and there is no time to change labels. Any communication of use applications would therefore have to take place through other means.

The lack of full understandingof behaviour in soil at this late stage in the development of the AI is of concern. The unexpected results with the copper salt require costly re-work. The Region and the PLT have responded swiftly and initiated the necessary remedial action.

8. *Mesotrione - Ames testing: status opposite EPA*

At the last review (DeCo, April 2002) the selective herbicide Product Line Head indicated that the high cost associated with the current practice (purification of NMSBA and Ames testing) was a problem and not likely to be acceptable long term. He had urged to find a solution that would not incur this cost penalty. GRA had undertaken to evaluate options and to recommend alternatives.

Regulatory situation in EU:

- Tox dossier: Mesotrione tech. is Ames -ve
- Xan1 is included in the specification (Limit: 0.0002%)
- Commitment regarding production: Xan 1 and, implicitly, other impurities will be kept to a level such that the final technical material contained levels below those of any toxicological concern (implicitly Ames negative)
- No commitment regarding Ames testing in production

Regulatory Situation NAFTA:

- Tox dossier: Mesotrione tech. is Ames –ve
- US-EPA has been informed about Xan1-Xan5
- Syngenta has made an implicit commitment to produce Ames negative material i.e. that keeping respective impurities below tox significant level (and below 0.1%, not on CSF)
- No commitment regarding Ames testing in production

Arguments loosening the strict limit of Ames 2:

- A batch of Mesotrione with an Ames response of 2.8 (mean) has been tested in long-term tox studies in rat and mice. It has been shown that this batch of Mesotrione is not carcinogenic
- Mesotrione PPZ-34 with an Ames response of 9 has been subject to in-vivo tests: negative
- There is variation in the Ames results of a given sample of Mesotrione and there might be variation between samples from one production batch. This variation could to be quantified experimentally, leading potentially to a range of acceptable Ames responses (e.g. Ames 1-3)

Ames results and statistical data supporting our position on a range of acceptable Ames responses will become available in due course, but there is no certainty that the authorities will accept the argument. There is the risk that they will request one or several of the following:

- Detailed explanation of what is specifically causing the Ames positive results
- Detailed questions on our Ames QC system
- Request for continued Ames testing

- Request for a limit of Ames 1.5 or less
- Additional tox data on Xan's
- Specific limits for Xan's
- Xan's to be included in the specification

Alternative: Replacing Ames testing by a Chemical Quality Control

- The impurity 2,5-DNMSBA is known to be the precursor to Xan1. Other dinitro-benzoic compounds in NMSBA are precursors for other Xan's
- A chemical QC on mesotrione and its impurities is not possible because we do not understand the causal link between the Ames response and the quantitative or qualitative profile of Xan's.
- ⇒ A chemical QC on NMSBA seems to be more practical than a chemical QC on mesotrione

Requirements for a chemical QC on NMSBA:

- ⇒ A standardized chemical QC on NMSBA
- ⇒ A standardized production process for mesotrione

The following steps are proposed:

- Specification of the NMSBA QC system, based on a validated correlation between NMSBA specs and resulting pattern of impurities in Mesotrione and the Ames response (ongoing)
- Establish a chem. QC of NMSBA based on the correlation between the sum of 2.4-DNBA and 2,5-DNMSBA and the nitroxanthenones in mesotrione as a group (mid Sept. to mid Nov)
- Establishing a standard production process + a protocol for initial Ames QC when changes in raw material and production are made (mid Sept. to mid Nov.)
- Establishing a convincing production and QC history (mid Sept. to mid Nov.)
- Preparation of draft Regulatory position (mid Sept.)
- Function review of technical positions and overall position (mid Oct.)
- Critique by consultant (mid Nov.)
- Presentation to DeCo (Dec.)

The team recommends the following approach:

- Continue Ames QC testing of Mesotrione
- Continue as proposed to work towards loosening the strict limit of Ames 2
- Replacing Ames testing by a Chemical Quality Control
- Define production-related protocols for
  - implementing process changes or
  - unexpected changes in production and the related changes in QC

Conclusion and recommendation:

The problem is proving even more complex than initially thought. Premature discussions with regulatory authorities could trigger additional requests for explanations and data or possibly even stricter quality control procedures.

For the time being we have no alternative to continuing with the existing testing programme, since NAFTA would not want, at least at this stage, to ask EPA for permission for selling Ames+ve material. This position is also supported by HAES as long as we do not clearly understand the reasons for the +ve response. The chemical QC test is not sufficiently robust at this point. Further work might bring this up to a real option – and perhaps could be linked with the *in-vivo* tests.

A new route to NMSBA is a potential possibility, but would be expensive and take time.

The fact that some Ames+ve material tested –ve in *in-vivo* studies does not automatically mean that all other batches would also prove –ve. To draw a generally valid conclusion, between about 10 and 20 production batches would have to be tested and show the same result. This

approach does appear to hold some promise as it could be used to persuade the regulatory authorities to allow the sale of weakly Ames+ve material.

8.1. Action: the chemical QC approach is not considered an option in the short term. The team is asked to consider instead the generation of data through a series of in-vivo tests. J. Street

9. NOA 407 855 - tox issues: status

The topic was presented by K. Pfister.

Chronic mouse study

The situation with the chronic mouse study has been reviewed; the acceptability of the study is considered to be at risk because of

- the low number of animals
- the cause of death is linked to dosing procedure
- the high level of technical management problems
- a (statistically) inconclusive evaluation of tissue changes

The acceptability will also depend on the judgement of reviewers who may follow different approaches.

Unless the decision to repeat the study is taken now, the market introduction is likely to be delayed by 2 years. Such a delay would seriously jeopardise the viability of the project
The economic rational for initiating a repeat study now appears acceptable:

Cost for repetition:	$ 1 Mio
Cost for 1 year delay:	$ 22 Mio
Cost for 2 years lost sales:	>> and unacceptable

The PLT therefore recommends to start a new chronic dietary feeding mouse study at Alderley Park as envisaged as a fall-back option in the master development plan.

The dose levels and the number of doses have not yet been agreed and cannot be presented.

Formulation Toxicity (skin)

- In vitro: The new EC100 and an EC60 variants have been tested as corrosive to the skin.
- In vivo: Both variants are irritant to the skin, but not corrosive.

The cause of corrosiveness (in vitro) has been identified by testing inerts/AI combinations in the skin irritation in vitro test:

- A unique interaction of Ca-DBS and tertrahydro-furfuryl alcohol.
- Both inerts are common components of typical EC formulations.

The team concluded that based on a classification as „irritant" to the skin there is no issue with developing these formulations further.

Formulation Tox (eye)

- Strong eye irritation remains a current issue
- EC100 will be classified as R41 (EU)
- Classification of the EC60 in tox category I is likely (NAFTA)
- A series of Ca-DBS free variants of the EC60, EC100 and EC120 are currently running at Alderly Park for *in-vivo* eye irritation testing

Biological results, phys.chem data and toxicological results are expected by early/mid October for decision making. So far an impact on the submission timeline is not expected.

9.1. Action: DeCo supports the initiation of a repeat mouse study. K. Pfister

10. LUMAX and CAMIX: release to first sales

Lumax rate of application and ratios

Product rates pints / acre	Mesotrione	S-metolachlor	Atrazine	Benoxacor
Ratio	1	10	3.70	0.5
1	37.35	373.5	138.2	18.675
6	224.1	2241	829.2	112.05
5	186.75	1867.5	691	93.375
4	149.4	1494	552.8	74.7

Lumax positioning

- Control of all important annual broadleaf and grass weeds in corn, including weeds resistant to ALS inhibitor, triazine and glyphosate herbicides.
- Season long control of *Abutilon* and *Amaranthus spp*. Give significant advantages over competition
- One application, pre-emergence or early post-emergence, will give season-long control through to canopy closure
- Excellent safety to corn
- Safety to key rotational crops; soybeans, cereals and sorghum
- Easy to use liquid formulation
- Flexibility to use on all corn hybrids and all soil types
- Low rate of triazine to meet latest regulatory conditions and rotational considerations

Lumax SWOT analysis

Strengths	Weaknesses
One-shot broad spectrum weed control Superior to acetochlor programs Competitive with Roundup Ready Exclusive to Syngenta	Formulation not optimum (esp. corrosivity, Cu) CoGs
Opportunities	**Threats**
Enhanced formulation Leverage sales of other products on basis of farmer pull for LUMAX	Carry-over to soybeans Roundup pricing Triazine restrictions

The only issues that have been identified relate to carryover (c.f. item 7). The formulation is corrosive to all metals except stainless steel. Large scale application tests with balk tanks and farm sprayers have been conducted with satisfactory results. The formulation is based on copper and there is scope for improving the cost in due course.

Stewardship Required

- A high level of product performance monitoring will be undertaken as with any major product launch
- Particular emphasis is being given to inspection of dealer bulk tanks and pumps and replacing them where required with stainless steel
- Specific monitoring of rotational cropping will be required
- Release to stage sales dependent on review of copper salt carryover data (end of September 2002)

- Review recommendations on carryover at October or November DeCo meeting

Risks	Who affected	Probability / Impact
Carryover potential of mesotrione copper salt	Farmer / Syngenta	Low if managed
Formulation issues (Tank corrosion / spray issues)	Farmer/Dealer / Syngenta	Low
Failure of one pass in very dry conditions	Farmer	Low
Round-up ready price decrease makes Lumax uncompetitive	Syngenta	Low
Benefits		
One pass pre-emergence weed control where two passes currently required	Farmer	High
Contains a rate of atrazine which is acceptable in most areas of the USA corn belt	Farmer	High
Regains market share lost to acetochlor	Syngenta	High
Unique product offer (no other one pass solution in target market)	Dealers / Syngenta	High

Camix rate of application and ratios

	[illegible]	[illegible]	[illegible]
Ratio	1	10	0.5
Pints/Acre	40	400	20
4	187.2	1872	93.6
4.8	224.4	2244	112.2

Camix positioning

- Control of a broad-spectrum of annual broadleaf and grass weeds in corn, including weeds resistant to ALS inhibitor, triazine and glyphosate herbicides
- Can be applied pre-emergence or early post-emergence and gives season-long control of sensitive weeds through to canopy closure
- Season long control of *Abutilon* and *Amaranthus spp*. Give significant advantages over competition
- Excellent safety to corn
- Safe to key rotational crops; soybeans, cereals and sorghum
- Easy to use liquid formulation
- Flexibility to use on all corn hybrids and all soil types
- Does not contain a triazine; can be used where triazines are not desired or allowed

Camix SWOT analysis

Strengths	Weaknesses
Broad spectrum weed control Triazine free Exclusive to Syngenta	Weed escapes in ~20% of cases Formulation not optimum (esp. Corrosivity, Cu) CoGs
Opportunities	**Threats**
Triazine restrictions	Carry-over to soybeans Roundup pricing

Risk	**Who affected**	**Probability / Impact**
Carryover potential of mesotrione copper salt	Farmer / Syngenta	Low if managed
Formulation issues (Tank corrosion / spray issues)	Farmer / Dealer / Syngenta	Low
Positioning / market fit not completely clear in USA	Syngenta	Low / Moderate
Benefits		
Provides excellent triazine free pre-emergence weed control	Farmer	High
Provides pre-emergence solution for markets where triazines are restricted banned (France)	Syngenta	High
Regains market share lost to acetochlor	Syngenta	High

Discussion and conclusions:

The two products are commercially important. The issues are similar.
There are no regulatory issues, but potential effects of carryover are of concern. Also the formulations are not optimum in terms of cost and properties.
The risks have been recognized and appropriate actions have been initiated. There is still a general concern that it may not be possible to attribute the risk of carryover entirely to the presence of copper in the formulation. It is also felt that if this should be the case that reducing the application rate by a few grams per ha may still not prevent the occasional occurrence of problems in the field under unfavorable conditions, since we have to assume that over spraying will occur in practice and knowing that the effects are rather visible.
There was some concern about the fact that these issues had been identified so late in development and that much effort during the launch phase would have to focus on safety aspects rather than on promoting the products as such.

10.1. Action: DeCo supports the launch of Lumax and Camix, but recommends to proceed carefully until full confidence has been gained that the issues identified are manageable. D. Cornes

10.2. Action: The release is provisional for one year and will be reviewed in the light of experience. D. Cornes

10.3. The provisional release is also subject to the availability of comprehensive plan of the stewardship measures that will be pursued to support the launch and use during the first season. D. Cornes/15.Oct. 2002

11. *Methidathion - user safety: status report*

The topic was presented by F. Tripet and M. Wilks. D. Wilde, J. Mcfarland and D. Castle also participated in the discussion.

Current sales of methidathion based products are as follows:

	2001 sales in $ Mio
Japan	17
Asia Pacific total	26.8
Latam total	4.0
EAME total	14.4
NAFTA total	< 1
Total global sales	**45.1**

Most sales occur in fruits and nuts ($ 34.5 Mio) and tropical plantations ($ 4 Mio)
Methidathion is on List 2 of the European review in the context of 91/414. Syngenta decided to support the compound and notified. The dossier has been submitted to the Portuguese authorities as the rapporteur member state in April 2002. Syngenta committed to deliver additional data on worker exposure by September 2002.
This operator exposure study in citrus / Spain has been completed and the data analysed.

Tier I: modelling showed overexposure with regard to AOEL in high standing crops.

TierII/III:

- Identification of most critical use pattern: gun application in citrus
- Passive dosimeter study: results showed some overexposure, further investigation became necessary
- Combined bio monitoring/passive dosimeter study performed in citrus. The bio monitoring results indicated the possibility of exposure exceeding levels generally considered acceptable in Europe. This does not equate to an impact on human health, but would clearly require additional operator protection to avoid high exposure during long-term practical use.

The team proposed the following action plan:

	EU	Rest of the World
Current strategy:		
End of Sept.	- Submitt to EU rapporteur. Obtain meeting with Rapporteur for mid October. Attitude: we want to defend the product	- Define new PPEs
	- Communicate internally with France	
1st half October	- Meeting with EU Raporteur	- Start Internal investigation of feasibility of new PPEs, country by country.
end of October	- Elaborate a phase-out plan for EU based on official deadlines (July 2003) - EU Rapporteur decides on pass / fail Completeness Check	
	- Syngenta decision on MTD Europe	
1st half November	- Communicate Syngenta decision to EU Rapporteur, Commission and other notifier	- Elaborate new labels and stewardship program for Selected Countries. Elaborate a phase-out plan for other countries.
	- Communicate internally to countries -> local trade	- Communicate global position internally to countries ROW
December	- Last sales in France	- Change labels in Selected Countries
Spring 2003		- Implement Stewarship / Monitoring program in Selected Countries and phase-out in other countries
July 2003	- Last sales in the EU	

Discussion and conclusion:
There was agreement that supporting the compound in Europe further would require considerable resources and that this was not an investment that could be recommended. It was also questioned, whether the level of personal protection that would be required to achieve the desired safety margin would prove practical under field conditions.

Under the circumstances an agreed and managed withdrawal, first from Europe, but in due course also from other countries was the preferred option.

11.1. Action: DeCo supports an agreed and managed withdrawal as proposed by the team. It is desirable to do this with the support of relevant authorities. The appropriate programme needs to be planned and resourced. F. Tripet

12. *Chlorothalonil - EU re-registration: status*

At least $ 13 Mio will have been spent on the support of the molecule from 1998 until the end of 2002. A further investment of about $ 4.5 Mio is envisaged during the next 3 years. The inclusion in Annex 1 in Europe is expected in mid 2003.

The key issues in Europe:

- **EU Acute Reference Dose proposal:**
  - Would lead to the loss of most uses on vegetables
  - Major threat to EU chlorothalonil business and the mixture strategy with mefenoxam
  - Specific ARfD study could solve EU situation, but would probably trigger Potentially Referable Findings (PRF)
  - EPA would likely want to review issues as well
  - Might trigger review of some endpoints not covered by current RED

Strategy:
- We need to decide approach to ARfD
- If a study needs to be done this requires discussion and agreement with NAFTA and full support of the PLT.

- We would need to consider what additional resources and investment might be needed to handle a potential review in NAFTA.

- **New guidance on metabolites in groundwater**
  - R 417888 exceeding proposed 10 ug/l Trigger for non-relevant metabolites in GW
  - Repeat applications at rates >1 kg/ ha are at risk

Strategy
- New efficacy studies at lower use rates (Bravo and mefenoxam mixture)
- Refined modelling
- Refine GAP for potatoes submitted under 91/414 based on realistic use rates

- **Stability of residues in processed food**
  - For some crops (legumes, pulses, brassicas) significant loss of residues during processing
  - Ongoing study to check issue dimension for the whole EU label
  - EU member states are informed on issue; no impact on the 91/414 review: Data on representative uses (potatoes/wheat) are available and acceptable since it is based on new method
  - Within NAFTA this is not perceived as a major issue
  - A new set of studies will definitively be required for LATAM

Strategy
- The issue requires additional funding; many of the old residue data do not reflect existing GAPs
- Focus on the key crops and review of the existing labels in view of the business opportunity

- **Regulations on HCB and other micro contaminants**
  - Canada has taken a lead in driving „virtual elimination target" under the POP convention for HCB and related chemicals (dioxin's, biphenyl's, bifuran's etc.)
  - Requirements exceed actual POP agreement
  - The new CTN specification for HCB at the level of 40 ppm which has been implemented is still considered as too high; the target virtually „0"
  - Increasing activities on the issue also noted in the USA, JP and Europe

Strategy
- Dossier submitted on HCB in Canada to improve HCB levels further (together with plans on atrazine)
- CTN Supply Chain & GRA team has set up team working on an aggressive AI improvement plan in GBB
- Potential for generic defense strategy heavily investigated

Additional concerns:
- Stability in air
- Global Stewardship issues and image problems internal and external
- Weakness of the chlorothalonil data base
- Pressure from generic producers
- Brazilian Review of chlorothalonil

Discussion and conclusions:

The need for additional efforts and funding is recognized. The fact that some of the generic competitors appear to take lead in establishing tight specifications for micro contaminants is of concern. Whilst we are constantly within the established specifications, we would not, at present be able to guarantee levels of 20 ppm or less. This is an area where additional effort appears justified.

13. ACANTO

a) Earthworm issue

The topic was presented by F. Lewis
Earthworm effects seen to date have been discussed at the June meeting.

Population Trials

- Effects on population at 1 month after application was observed in up to half of the 9 trials established in France
- Effects were seen even in the absence of any visible surface mortality and under generally dry conditions
- Effects >30% at 1 month in 5/9 sites (4/9 sites at 250 and 2/9 at 125 g AI/ha).
- Some indication of a dose response in magnitude of effect
- Recovery of populations to be determined in further sampling

Recovery Trials following Forced Effects

- Surface effects achieved at all three sites
- Limited population data available to date (1 month sampling from only 1 of 3 trials)
- Data indicates population effects at all doses (62.5 to 500 g AI/ha) but with some evidence of dose response
- Surface mortality does not account for full extent of population effect

Predicted Risk vs Field Effects

Standard risk assessment assumes 50% crop interception and chemical evenly distributed in top 5 cm of soil. Soil residue analysis from "forced" trials confirms 50% crop interception but picoxystrobin found predominantly in top 1 cm of soil even under wet conditions.

This level is above the corrected NOEC from the laboratory study using standard laboratory species in standard soil, which may be less sensitive than field species in field soils.

Residue analysis of dead earthworms confirms no risk of secondary poisoning to birds and mammals.

Duration of Acute Effect

- Data indicates that surface effects occur within 4-8 days following application
- Even if there is significant rainfall after this time – no further surface effects have been observed
- DT50 in soil would indicate toxic levels are still present beyond 8 days

⇒ This indicates that picoxystrobin may remain bio-available to earthworms for only a few days after application

⇒ This hypothesis fits for surface effects but we cannot yet assess if also true for overall population effects.

Potential for Recovery

The key endpoint of concern for earthworms is recovery and current technical opinion (and regulatory guidance) regards effects to be acceptable providing recovery is demonstrated within 1 year.

Recovery trials are ongoing with the first data to judge recovery (4 – 5 months after treatment) expected in October. The current judgment is that recovery of the affected earthworm populations within one year is anticipated, at least up to rates of 1 x 250g AI/ha.

b) Acanto Dos - Release to first sales

The topic was presented by I. Dalton

Lead AI:	Picoxystrobin
Manufactured at	Grangemouth

To be sold as a pre-formulated mixture
125 g/l Picoxystrobin +
125 g/l Hexaconazole
Packaging configuration: 4 x 5 litre and 1x20 litre
For use on wheat and barley in France
Registration certificate is expected in November 2002

Acanto Positioning

- Systemic, strobilurin fungicide controlling a broad spectrum of foliar diseases
- Providing lasting disease control
- Curative and preventive activity
- Uniform protection of the crop and protection of new growth to the flag leaf stag
- The T1 solution for wheat
- Complete spectrum of early season foliar diseases and unsurpassed for yields
- The outstanding strobilurin for barley

Projected Sales:

US$ mio	2002	2003	2004	2005
Sales	3.9	12.5	9.9	2.1
Gross Profit	1.2	4.1	3.5	0.8
Gross Profit %	30	33	36	39
Business contribution	0.8	3.2	2.8	0.7
Business contribution %	21%	26%	28%	31%

Use of Acanto Dos:

- Label rate for ACANTO Dos is 2.0 l/ha – one application per season (restricted by hexaconazole registration)
- Growers likely to use 1.0 to 1.5 l/ha in combination with UNIX, GARDIAN
- Product promotion will focus on early use in wheat
- Normally GS 30 – 32 (T1) or as first spray of season up to GS 37 (early T2)
- On barley emphasis will be on early season use
- The product of choice where one spray is used
- Program with AMISTAR when there are two sprays
- Good crop safety; compatible with a broad range of products
- Multiple tank mixes or aggressive surfactants may cause transient paling in wheat

Safety profile:

- Low toxicity - will not be classified
- Safe to operators / workers
- Residues in grain are low
- Safe to consumers
- Rapidly degraded in soil
- No persistent metabolites
- No leaching to groundwater
- Negligible risk to non-target organisms under field conditions

Issues and actions

Earthworms:

- Proactively address earthworm tox with regulatory authorities
- Bring confidence to internal and external stakeholders that the problem is understood and manageable
- Have ready a sound plan and communication network to be able to react quickly and judiciously to any "in-use" issue

Transient paling observed in wheat:

- Manage through advice on tank mixtures and early season spray timing

Discussion and conclusions:

Acanto Dos represents an opportunity for incremental business in wheat and barley and is in line with the planned phase out of hexaconazole. The product offers competitive product performance in wheat and barley and represents and excellent technical fit with targeted market position

The issues that have been identified appear manageable. It has to be noted, however that although it can be expected that the toxicity of the mixture to earthworms will be driven by picoxystrobin it would have been useful to have the results of a laboratory formulation toxicity study on earthworms.

With the exception of the results from a bee study which indicate that this formulation appears to be more toxic to bees than the individual AIs, all other studies indicate toxicity within range predicted from individual AIs

A laboratory earthworm study is now planned on Acanto Dos for early next year and for all future mixture formulations of picoxystrobin, an acute lab worm study is recommended.

Acanto Dos was included in the efficacy trials conducted in France in 2001 and surface mortality observed on plots treated with Acanto Dos were of a similar magnitude to that seen with straight Acanto (but data is sparse). Risk to earthworms in the field is unlikely to be significantly different from Acanto.

All relevant countries have been informed of the effects, but the authorities did not appear to be particularly alarmed; however they clearly expect to receive information that shows that populations recover within one year.

In case we are forced to add a warning to the label this would affect the image of the products adversely. If the positioning had to change, e.g. single application, rate reduction or later application, the total opportunity could be reduced by more than half from the currently $ 115 Mio.

It was pointed out that efforts had to made to stem the negative impressions that have apparently spread in some places/countries. The problem needs careful stewardship, but should not be exaggerated. We also need to monitor the activities of competitors to enable us to react if they should try to exploit the situation unfairly.

Whilst it would be desirable to restrict the use following heavy rainfall, it was considered impractical, since growers will buy products in advance and do not have the flexibility to change at short notice.

13.1. Action: DeCo supports the release provisionally for 1 year, subject to satisfactory population recovery data later this year. I. Dalton

13.2. Action: Efforts should be made to bring forward the planned laboratory earthworm study. The results should be available before the product is applied in the field. K. Mewes

13.3. Action: J. Atkin will be briefed on the latest situation. V. Anthony

13.4. Action: Sessions need to be arranged with key countries to ensure our own people understand the situation and are able to respond professionally. P. Huguet/I. Dalton.

14. Miscellaneous

a) Process for the generation of technical summaries for submission in 'Secondary' countries

Risk assessment is generally driven by the needs of primary countries. If information for secondary countries is not available, they either have to compete for resource or develop their own positions. The latter may lead to a divergence from the compete Syngenta position.

Recommendation

`Secondary` risk assessments are generated at the same time as primary ones and entered into SAMSON by GRA. The incremental HAES resource is not expected to be that much greater, but efficiency and effectiveness will be improved.

14.1. Action: The proposal is supported and the new approach will be accommodated in future work plans. L. Smith for communication within HAES and J. Street in GRA

b) SYPOS: status

A modified project proposal has been presented to the CSP2 leadership team on 27 August. This envisaged a migration of the new Syngenta portfolio management system from an in-house technology to an emerging new Microsoft platform (Microsoft Project 2002). The main advantages seen are:

- Competitive advantage through the use of a state-of-the-art, commercial project and portfolio management support tool; opportunity to re-design (overly) complex business processes and to achieve a degree of uniformity across the organisation.
- Chance to realise a fully integrated IS environment with the advantage of working with one set of data.
- Effective team, issue, data and document management and workflow support – a critical success factor in a global project oriented organisation.
- Ability to focus on core activities (rather than tool development and support)
- World-class tool - high probability of user acceptance
- Assured up-dates reflecting technological advances with minimum disruption and compatibility problems

The CSP2 Leadership team supported the proposal, but since the investment exceeded the group's authorization limit, it will have to be presented also to the full SEC on October 3.

c) Access to DeCo shared folder

Following the Schluchsee Development Managers meeting it had been agreed that the DeCo agenda and the minutes will be circulated more widely and that in particular all participants of

the meeting would be on the distribution list. A number of colleagues also requested access to the shared folder, which contains all the pre-reading material and copies of the presentations. It is recognised that some of this material is highly confidential and could harm the Company's interest if used inappropriately. On balance it was felt, however that the benefits outweigh the risk and that the information should be made accessible.

14.2. Action: Provide access to the DeCo shared folder to all recipients of the DeCo minutes. A. Kohli

15. Actions

Topics for 2002 DeCo Meetings

Date	Agenda item	DeCo Contact	Responsible	Docs
Oct. 15	1. Az – allergen project: Stage B promotion	AK	Yoder Joe CHBS; Schabacker Dan CHBS;	
	2. Thiamethoxam - non-crop: project review	AK	Yoder Joe CHBS; Schabacker Dan CHBS;	
	3. Abamectin - formulation projects (nematodes/non-EC/slug bait): project review	AK	Gillham Malcolm CHBS; Hofer Dieter CHBS	
	4. Picoxystrobin - fruits: up-dated project status	AK	Huggenberger Fritz CHBS	
	5. Emamectin Benzoate - AI cost reduction: project review	AK	Arslan-Bir Martine; CHBS; Schmidt Elke-1 CHBS;	
	6. Acuron: project review	AK	Vitolo David CHBS; Barnes Jasper CHBS;	
	7. Butafenacil: project review	AK	Molitor Elvira CHBS;Vitolo David CHBS; Barnes Jasper CHBS;	
	8. Trifloxysulfuron - HTC in rice: project review	AK	Maurer Willy CHBS; Howard Stott CHBS;	
	9. Clodinafop - life cycle, EU re-registration: status	JS	Brandl Matthias CHBS; Allen James CHBS; Pfister Klaus CHBS	
	10. Portfolio 2002 – Non-AI related activities: agree appropriate resource allocations ✓	AK	all	

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Date	Agenda item	DeCo Contact	Responsible	Docs
Nov. 21	1. Trifloxysulfuron - Review of first year's sales	AK	Maurer Willy CHBS; Allen James CHBS	
	- Sales release USA (cotton & turf)	AK	Zajac Mark CHBS; Schabacker Dan CHBS	
	2. NOA 407 855: project review	AK	Coulon Antoine CHBS;	
	3. Az – allergen project: Stage B promotion	AK	Yoder Joe CHBS Schabacker Dan CHBS	
	4. Mesotrione: stage 4 promotion	AK	Garrett Judy J CHBS;	
	5. Lufenuron - EU re-registration (pending February decision), - Match development in Australia – project review	JS	Duan James CHBS; Moreau Michele CHBS	
	6. Lambda Cyhalothrin - EU re-registration: status report	JS	Stepan Michael CHBS;	
	7. Paraquat - Stewardship activities (Gramoxone Image Projects): status report	MB	Voerman Michael CHBS; Barnes Jasper CHBS	
	8. Touchdown – Innovation: project review	VA	Lawton Tina CHBS;Barnes Jasper CHBS	
	9. Picoxystrobin: up-dated project status	AK	Dalton Ian Paul CHBS; Huggenber Fritz CHBS	
	10. Pyriftalid – APIRO: brands in Japan	AK	Amrein Josef CHBS;	
	11. Thiamethoxam - Asia Rice project: project review	VA	Camblin Philippe CHBS; Senn Robert CHBS;	
	12. Thiamethoxam - mixture formulations: project	VA	Camblin Philippe CHBS; Senn Robert CHBS;	
	13. NOA 446510: up-dated project status	AK	Huggenberger Fritz CHBS	
	14. Formulation development inert strategy: follow-up		Gordon Paul CHBS	

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	15. Ffybes – technical review and Stage Plan progression: promotion to Stage xxx	VA	Wilde Rob CHBS Barnes Jasper CHBS	
Dec. 13.	1. SYN 449 280; promotion to Stage 3 2.	AK	Garrett Judy CHBS Zoschke Andreas CHBS Weber Hans	

Topics for 2003 DeCo Meetings

Date	Agenda item	DeCo Contact	Responsible	Docs
Feb. 5	1. Review of initiatives across Syngenta aimed at influencing the development of regulatory policies	JS	Street John CHBS	
	2. Water and dietary exposure issues – establish an agree Syngenta policy and assess impact of developing legislation on the Syngenta product range	JS	Street John CHBS	
	3.			
March 26	1.			
May 7	1.			
August 6	1.			
Oct. 8+9	1.			

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